K011834

JUL 1 0 2001

510(k) SUMMARY **Date Prepared: June 11, 2001**

Company Name and Address

Aspect Medical Systems, Inc.
141 Needham St.
Newton, MA 02464

Contact Person: Christine M. Vozella
Director, Regulatory Affairs/Quality Assurance

Device Name

Proprietary Name: BIS Engine (PCB component in an EEG Monitor)
Common Name: EEG Monitor

Classification

Electroencephalograph (EEG) monitors and their software have been classified by the Neurological Devices Panel as Class II devices (21 CFR 882.1400)

Predicate Device

BIS Engine	K002837, FDA cleared September 19, 2000
A-1000 EEG Monitor with 4 channel amplifier (DSC-4)	K923043A, FDA cleared December 3, 1992

Device Description

The Aspect Medical Systems, Inc. BIS Engine - 4 channel support provides the means for incorporating Aspect's proprietary BIS technology into OEM (original equipment manufacturer's, i.e. our business partner's) finished devices. It is a small printed circuit board (PCB) that can either reside inside the OEM finished device or is re-designed for smaller size and packaged in a housing that will connect to the OEM finished device.

The fundamental scientific technology has not changed. The BIS technology remains the same. The BIS Engine - 4 channel support (subject of this 510(k)) has the same basic function, and same operating principal as the Predicate Device.

Only the software is changing. More specifically, the only difference is that the BIS Engine (subject of this 510(k)) can process up to 4 channels of EEG, compared to the Predicate Device, which can process up to 2 channels of EEG. The BIS processed parameter will only be calculated when in 2 channel maximum mode.

Intended Use

Intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Summary of Technological Characteristics Compared to Predicate Device

The BIS Engine - up to 4 channel support is substantially equivalent to the Predicate device (BIS Engine - up to 2 channel support).

Similarities

The fundamental technology has not changed. The indications for use are the same. The BIS technology remains the same. The BIS algorithm is the same. The BIS Engine has the same parameters, same operating principle, and same signal processing design. The hardware design is the same. The electrical and mechanical designs are the same.

Minor Differences

Only the software is changing. More specifically, the only difference is that the BIS Engine (subject of this 510(k)) can process a maximum of 4 channels of EEG, compared to the Predicate Device, which can process a maximum of 2 channels of EEG. The BIS processed parameter will only be calculated when in 2 channel maximum mode.

The following analysis and validation was performed:

1) Risk analysis
2) Software validation

Results of risk analysis: There are no additional hazards introduced by the BIS Engine - 4 channel that are severe enough to warrant tracking on the risk management record.

Results of validation: The applicable testing was completed (the modified BIS Engine will be a component to a finished device owned by our business partners, and as such, there are no patient or user safety concerns due to the BIS Engine in and of itself).

Results show all tests are acceptable.

The BIS Engine - 4 channel support is substantially equivalent to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 0 2001

Ms. Christine M. Vozella
Director, Regulatory Affairs/Quality Assurance
Aspect Medical Systems, Inc.
141 Needham Street
Newton, Massachusetts 02464

Re: K011834
Trade/Device Name: Aspect Medical Systems, Inc. BIS Engine
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: June 11, 2001
Received: June 12, 2001

Dear Ms. Vozella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K011834

Device Name Aspect Medical Systems, Inc. BIS Engine (4 channel support)

Indications for Use

Intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011834

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)